to PTO, the applicant, and the petitioner.

(b) FDA may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 60.30;

(2) The petition is not filed in accordance with § 10.20;

(3) The petition does not contain the information required by § 10.30;

(4) The petition fails to contain information or allegations upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period; or

(5) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence such that, even if the petition were granted, the petition would not affect the maximum patent extension the applicant sought in the application.

### § 60.36 Standard of due diligence.

(a) In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. FDA will take into consideration all relevant factors, such as the amount of time between the approval of an investigational exemption or research permit and the commencement of a clinical investigation and the amount of time required to conduct a clinical investigation.

(b) For purposes of this part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant or applicant for patent term restoration shall be imputed to the applicant for patent term restoration.

## Subpart E—Due Diligence Hearings

### § 60.40 Request for hearing.

(a) Any person may request, not later than 60 days after the publication under § 60.34(a) of FDA's due diligence determination, that FDA conduct an informal hearing on the due diligence determination.

(b) The request for a hearing under this section shall:

(1) Be sent by mail, personal delivery, or any other mode of written communication to the Division of Dockets Management and filed under the relevant product file;

(2) Specify the facts and the action that are the subject of the hearing;

(3) Provide the name and address of the person requesting the hearing; and

(4) Certify that the requesting party has served a true and complete copy of the request upon the petitioner and the applicant by certified or registered mail (return receipt requested) or by personal delivery.

(c) The request shall state whether the requesting party seeks a hearing within 30 days or 60 days of FDA's receipt of the request.

[53 FR 7305, Mar. 7, 1988, as amended at 67 FR 9585, Mar. 4, 2002]

### § 60.42 Notice of hearing.

Ten days before the hearing, FDA will notify the requesting party, the applicant, and the petitioner, orally or in writing, of the date, time, and location of the hearing. The agency will provide the requesting party, the applicant, and the petitioner with an opportunity to participate as a party in the hearing.

### § 60.44 Hearing procedures.

The due diligence hearing shall be conducted in accordance with this part, supplemented by the nonconflicting procedures in part 16. During the due diligence hearing, the applicant and the petitioner shall enjoy all the rights and privileges accorded a person requesting a hearing under part 16. The standard of due diligence set forth in § 60.36 will apply in the due diligence hearing. The party requesting the due

diligence hearing shall have the burden of proof at the hearing.

**§ 60.46 Administrative decision.**

Within 30 days after the completion of the due diligence hearing, the Commissioner will affirm or revise the determination made under § 60.34(a) and will publish the due diligence redetermination in the FEDERAL REGISTER, notify PTO of the redetermination, and send copies of the notice to PTO and to the requesting party, the applicant, and the petitioner.

# PART 70—COLOR ADDITIVES

## Subpart A—General Provisions



## Subpart B—Packaging and Labeling



## Subpart C—Safety Evaluation



AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 360b, 361, 371, 379e.

SOURCE: 42 FR 15636, Mar. 22, 1977, unless otherwise noted.

## Subpart A—General Provisions

**§ 70.3 Definitions.**

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) *Act* means the Federal Food, Drug, and Cosmetic Act as amended.

(e) *Color Certification Branch* means the unit established within the Food and Drug Administration located in the Center for Food Safety and Applied Nutrition, charged with the responsibility for the mechanics of the certification procedure hereinafter described, and including the examination of samples of color additives subject to certification.

(f) A *color additive* is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the transmittal of the color to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as *color additives*; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a *color additive*. Food ingredients as authorized by a definitions and standard of identity prescribed by regulations pursuant to section 401 of the act are *color additives*, where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such